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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/392,728	09/09/99	STOCKEMANN	K SCH-1550-C1

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EXAMINER

NGUYEN, H

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/15/00 *3*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/392,728

Applicant(s)

STOCKEMANN ET AL.

Examiner

Helen Nguyen

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-32 and 47- 49 drawn to a contraceptive composition and kit which employs a progesterone antagonist / gestagen multi-phase combination preparation, classified in class 514, subclasses 170 and 171.
- II. Claims 33-46, drawn to a method for contraception in a female mammal employing a progesterone antagonist / gestagen sequential administration regimen, classified in class 514, subclasses 170 and 171.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed in contraception could be practiced with another materially different product such as one containing estrogens and progestins.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

Specie Election

Claims 1 to 49 are generic to a plurality of disclosed patentably distinct species comprising A) Competitive progesterone antagonists and B) Gestagens. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of A) and B) above which are useful in the instant combination such as the different structures of competitive progesterone antagonist compounds of each specie below are separately classified, even though this requirement is traversed:

A) Competitive progesterone antagonist species:

- i) 1) ~~17 α~~ -ethinyl-17 ~~β~~ -hydroxy-11 ~~β~~ -(4-methoxyphenyl)estra-4,9-dien-3-one,
- ✓ 2) 11 ~~β~~ -(4-acetylphenyl)-17 ~~β~~ -hydroxy-17 ~~α~~ -(1-propenyl)estra-4,9-dien-3-one,
- 3) (Z)-11 ~~β~~ -(4-acetylphenyl)-17 ~~β~~ -hydroxy-17 ~~α~~ -(3-hydroxy-1-propenyl)estra-4,9-dien-3-one,
- 4) 11 ~~β~~ -(4-dimethylaminophenyl)-17 ~~β~~ -hydroxy-17 ~~α~~ -(1-propenyl)estra-4,9-dien-3-one,
- 5) (Z)-11 ~~β~~ -[4-(dimethylamino)phenyl]-17 ~~β~~ -hydroxy-17 ~~α~~ -(3-hydroxy-1-propenyl)-estr-4-en-3-one, classified in class 514, subclass 179.
- ii) 1) (Z)-9,11 ~~α~~ -dihydro-17 ~~β~~ -hydroxy-17 ~~α~~ -(3-hydroxy-1-propenyl)-6'-(3-pyridinyl)-4'H-naphth[3',2',1':10,9,11]estra-4,9(11)-dien-3-one, classified in class 514, subclass 176.
- iii) 1) 4',5'-dihydro-11 ~~β~~ -[4-(dimethylamino)phenyl]-6 ~~β~~ -methylspiro[estra-4,9-dien-17 ~~β~~ , 2'(3'H)-furan]-3-one,
- 2) 4',5'-dihydro-11 ~~β~~ -[4-(dimethylamino)phenyl]-7 ~~β~~ -methylspiro[estra-4,9-dien-17 ~~β~~ , 2'(3'H)-furan]-3-one, classified in class 574, subclass 173.

Art Unit: 1617

- iv) 1) 11~~β~~₂-(4-acetylphenyl)-19,24-dinor-17,23-epoxy-17~~α~~-chola-4,9,20-trien-3-one, classified in class 514, subclass 172.

B) Gestagen compound species:

- i) 1) norgestimate, 2) desogestrel, 3) 3-ketodesogestrel, classified in class 514, subclass 182.

- ii) 1) dienogest, classified in class 514, subclass 181.

- iii) 1) gestodene, 2) levonorgestrel, classified in class 514, subclass 179.

- iv) 1) cyproterone acetate, 2) chlormadinone acetate, 3) norethisterone, 4) norethisterone acetate, classified in class 514, subclass 178.

- v) 1) progesterone, classified in class 514, subclass 177.

- vi) 1) drospirenone (dihydrospirorenone), classified in class 514, subclass 175.

The search for all species presents an undue burden on the office due to the structural dissimilarity of the species and their correspondingly separate classification.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30 Eastern Time.

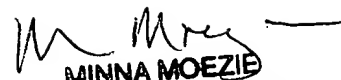
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, J.D. , can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Application/Control Number: 09/392,728
Art Unit: 1617

Page 6

Helen Nguyen
Patent Examiner
August 8, 2000.


MINNA MOEZ
PRIMARY EXAMINER